

**REMARKS**

Claims 99-104 and 107-123 are currently pending in this application after entry of this paper. Claims 99-101 and 103 have been amended to further clarify the subject matter of the claimed invention. Claims 107-115 have been withdrawn from consideration. Applicants reserve the right to pursue the subject matter of the withdrawn claims in a subsequent patent application. No new matter has been introduced by the amendments. These amendments are supported throughout the instant specification. (See, e.g., Example 4, pages 92-99.) Additionally, claims 116-123 have been added, and these claims do not contain any new matter. Support may be found throughout the instant specification. (See, e.g., Example 4, pages 92-99; page 37 of the translated priority document (German Application No. 102 54 601.0); and pages 41-42 of the instant specification.) Applicants respectfully request reconsideration in view of the above claim amendments and the following remarks.

**Priority**

The Examiner contends that the German Application No. 102 54 601.0 does not provide enabling support for diagnosing a cancer by detecting SEQ ID NO:16 (claudin 18A2.1). Applicants respectfully disagree.

The priority application, German Application No. 102 54 601.0, sets forth that SEQ ID NO:16 encodes the claudin-18A2.1 translation product that "can be used as a marker to detect tumors of the upper gastrointestinal tract, in particular stomach carcinoma and pancreatic carcinoma." (See Example 4, page 67, lines 15-20.) There is sufficient support within this application to show a correlation of mRNA levels and the protein that is translated by said mRNA. (See Example 1, pages 59-62 and Example 4, pages 67-70.)

The Examiner states that the PCT application from which this application claims priority does not meet the requirements of PCT article 11 because it was not published in the English language. Applicants respectfully disagree with the Examiner's interpretation of PCT article 11. PCT article 11 states that the PCT application must be filed "in the prescribed language." German is one of the accepted languages of the PCT receiving offices, particularly the European patent office where this application was

submitted. Thus, this application was submitted in an acceptable language and should receive the priority date of German Application No. 102 54 601.0. Furthermore, applicants respectfully point out that an English language translation of the U.S. national phase entry application was filed concurrently with the German PCT application in the U.S. receiving office on May 20, 2005. In view of the above facts, applicants respectfully request that the instant specification claims the benefit of both the PCT and German priority dates, November 21, 2003 and November 22, 2002, respectively.

**Response to 35 U.S.C. §112 Rejection, First Paragraph- Enablement**

Claims 99-104 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully disagree. However, in order to expedite prosecution without disclaimer of or prejudice to the subject matter recited in the instant application, applicants have amended the claims. Specifically, claims 99-101 have been amended to disclose a methodology of diagnosing stomach, lung, and pancreatic cancers. Thus, applicants respectfully argue that the Examiner's rejection has been rendered moot.

The Examiner states that the instant specification enables the diagnosis of stomach and lung cancers. (See page 4 of the Office Action dated June 27, 2007). The applicants respectfully argue that the diagnosis of pancreatic cancer is also enabled in the instant specification. (See Example 4, pages 67-70 of the translated priority document (German Application No. 102 54 601.0); and Example 4, pages 92-99 of the instant specification.) Additionally, the applicants respectfully argue that the diagnosis of esophageal cancer is also enabled in the instant specification. (See Table 3A of the instant application, page 94.) Independent claim 99 has been amended to recite a method of diagnosing stomach, lung, and pancreatic cancers. Independent claim 117 recites a method of diagnosing esophageal cancer.

Applicants respectfully argue that the instant specification, specifically Example 4, provides a complete description so that a skilled artisan can make and use the claimed invention. Reconsideration and withdrawal of these §112 enablement rejections are respectfully requested.

**Response to 35 U.S.C. §112 Rejection, First Paragraph- Written Description**

Claims 99-104 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner contends that these claims lack an adequate written description because the claims allowed for the detection of a portion of the claudin-18 nucleic acid. Applicants respectfully disagree. However, in order to expedite prosecution without disclaimer of or prejudice to the subject matter recited in the instant application, applicants have amended the claims for clarity. Specifically applicants have amended independent claim 99 which is now directed to detecting the expression of a tumor-associated antigen in a biological sample, where the tumor-associated antigen is either the polypeptide of SEQ ID NO:16 or a polypeptide encoded by a nucleic acid of SEQ ID NO:7.

Applicants believe that the instant specification provides an adequate written description so that one skilled in the art would understand that the applicants had possession of the claimed invention at the time that the instant application was filed. Reconsideration and withdrawal of these §112 written description rejections are respectfully requested.

**Response to Claim Objections**

Claim 103 has been objected to because there is a period after the word “a” before the end of the sentence. This claim has been amended to remedy the informality. Applicants respectfully request reconsideration and withdrawal of this objection.

### **Dependent Claims**

Applicants have not independently addressed all of the rejections of the dependent claims. Applicants submit that for at least similar reasons as to why independent claim 99 from which all of the dependent claims 100-104 depend are believed allowable as discussed *supra*, the dependent claims are also allowable. Applicants submit that for at least similar reasons as to why independent claim 117 from which all of the dependent claims 118-122 depend are believed allowable as discussed *supra*, the dependent claims are also allowable. However, applicants reserve the right to address any individual rejections of the dependent claims and present independent bases for allowance for the dependent claims should such be necessary or appropriate.

Thus, applicants respectfully submit that the invention as recited in the claims as presented herein is allowable and respectfully request that the respective rejections be withdrawn.

### **CONCLUSION**

Based on the foregoing amendments and remarks, the applicants respectfully request reconsideration and withdrawal of the pending rejections and allowance of this application. The applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendment and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided. Favorable action by the Examiner is earnestly solicited.

**AUTHORIZATION**


The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 4883-0001.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 4883-0001.

Respectfully submitted,  
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Dated: August 27, 2007

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